EMERGING CHALLENGES FOR U.S. MARINE BIOTECHNOLOGY

Robert W. Knecht*, Biliana-Cicin-Sain, and Dosoo Jang**
****Center for the Study of Marine Policy, University of Delaware***
*****National Oceanic and Atmospheric Administration***

Biotechnology has become a rapidly burgeoning industry worldwide.[1] It is expected to have profound impacts on health, agriculture, and aquaculture, by improving food products, enhancing environmental bioremediation, curing fatal diseases, and bringing potential socio-economic changes. Although still in the incipient stage, the field of biotechnology stands at the threshold of the next 'biotech century.'[2]

It is assumed that most of the issues applicable to the biotechnology field in general will also be applicable to marine biotechnology, because the latter can simply be defined as biotechnology applied to marine living organisms.[3] Marine biotechnology has recently been embraced as a field of great potential by molecular biologists and by the biotechnology industry because the oceans, covering nearly 70% of the earth surface and comprising 90-95% of the biosphere by volume of living organisms on earth,[4] contain a tremendous range of diverse biological resources and unique resources and conditions—for example, the largely unexplored deep-sea hydrothermal vents, and extreme ocean environments such as cold polar waters and the deep ocean floor characterized by intense pressure.[5]

Marine biotechnology has recently been embraced as a field of great potential by molecular biologists and by the biotechnology industry because the oceans...contain a tremendous range of diverse biological resources and unique resources and conditions...

In spite of the increasing attention on the part of molecular scientists and industry on the potential development of marine biotechnology, there are no coherent guidelines, framework conventions, guiding norms or principles to specifically govern the conduct of marine biotechnology development neither in the United States nor in other countries. A number of existing international agreements related to maritime jurisdictions, protection of biodiversity, and intellectual property, however, will significantly affect the operations of the U.S. marine biotechnology industry both in the U.S. and in the jurisdictions of other nations.

We see three important emerging issues or challenges which will affect the path of development of the marine biotechnology industry: 1) access to marine resources / organisms; 2) biosafety; and 3) intellectual property rights.

Issues of Access to Marine Genetic Resources/Organisms

The Convention on Biological Diversity (CBD)[6] and the 1982 Law of the Sea Convention (LOS Convention) are important treaties in the emerging international marine biotechnology field. The regime for governing access to marine resources / organisms under the jurisdiction of coastal nations for marine biotechnology purposes (both for samples and experimental research and for harvesting and production purposes) is in the process of redefinition. Traditionally, access to marine resources / organisms found within other nations' 200-mile Exclusive Economic Zones has been relatively easy and was governed under the terms of the 1982 LOS Convention which entered into force in 1994. Articles 237 through 265 provide that nations conducting scientific research get advance permission from the coastal nations in whose ocean zones such research is to take place. Provisions for sharing of benefits derived from the research under the LOS Convention only call for such measures as promotion of the flow of scientific data and information, the transfer of knowledge resulting from marine scientific research (especially to developing states), and the strengthening of autonomous marine science research capability of developing states (such as including local scientists in research cruises).

In contrast, the CBD paves new ground in international norms governing access to genetic resources, defined as "genetic material of actual or potential value." The Convention calls for the conservation of

biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. The CBD recognizes the sovereign right of nations to control access to their genetic resources, and requires the users of genetic resources to take measures to promote equitable sharing of the benefits, including technologies, with the providers of those resources.

There is thus a current need to harmonize the provisions of the LOS Convention and the CBD regarding marine biotechnology prospecting and any follow-on activities that may be involved. It would seem desirable, from the standpoint of the development of the field of marine biotechnology, for coastal nations to agree on the properties of a unified regime governing access to marine organisms, and perhaps, formalize it as a protocol to the CBD. As part of the development of such a protocol, nations will have to face the difficult question of valuing the information contained within particular marine organisms relative to the R & D investment of the prospecting firm (both before and after prospecting) as it attempts to decode the organisms, determine any unique properties they possess, and where it can, develop those unique attributes into useful products or services.

...there is currently a major effort underway to develop an international agreement on safety in biotechnology...which calls for "the safe transfer, handling, and use of any living modified organisms resulting from modern biotechnology."

Another important issue relates to access to marine genetic resources / organisms in the deep seabed. There is a controversy whether the exploitation of hyperthermophiles in the deep seabed would fall under the LOS regime regarding marine scientific research, the deep seabed mining regime, the high seas fisheries regime, or whether a new regime is needed.

Unfortunately, the U.S. is not currently in a position to play an effective international role in harmonizing the provisions of the LOS Convention and the Biodiversity Convention concerning marine biotechnology since it is not yet a party to either convention. While the U.S. can participate as an observer at the meetings of both conventions, in the continued absence of ratification of these treaties, it will be difficult for the nation to significantly affect the interpretation and implementation of these conventions.

Issues of Biosafety

The greatest controversies surrounding the issue of safety in biotechnology (or "biosafety" as the issue has become known) have focused on the development of living modified organisms (LMOs) through modern biotechnology techniques. Contained use and field release have been distinguished as the main categories of intended use of LMOs. Biotechnology has been developed and applied under contained conditions since the early 1970s, and for direct applications and release in the environment since the mid-1980s. Under contained conditions, LMOs are developed and employed for research purposes and are regulated by well-established risk-management techniques for work in a laboratory environment. The field testing of LMOs, on the other hand, continues to pose questions about the interaction of LMOs with natural ecosystems, such as with respect to: possible unintended changes in the competitiveness of natural species; virulence or other characteristics of targeted species; possibility of adverse impact on non-targeted species and ecosystems; stability of the inserted genes.

Internationally, there are as yet no binding international agreements to address the transboundary movement of LMOs. However, given the rapid development in the use of biotechnology, the lack of sufficient knowledge regarding the interaction between LMOs and the environment, the problems which may exist with LMO transboundary movement, and growing concern of the developing countries (the major source of genetic raw materials) that they could be used as LMO testing grounds, there is currently a major effort underway to develop an international agreement on safety in biotechnology. This is taking place under the aegis of the Convention on Biological Diversity, which calls for "the safe transfer, handling, and use of any living modified organisms resulting from modern biotechnology." CBD's Article 8(g) requires contracting parties to "establish or maintain means to regulate, manage, or control the risks associated with the use and release of living modified organisms resulting

from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health," and, in the past several years, negotiations have been underway to produce a legally-binding protocol on biosafety under the CBD.

After the Sixth Meeting of the Open-Ended Ad Hoc Working Group on Biosafety (BSWG-6) held from February 14 to 22, 1999, in Cartagena, Colombia, the first Extraordinary Meeting of the Conference of Parties (Ex-COP) to the CBD was held February 22-23, 1999, at the same venue and attempted to finalize a protocol on biosafety for adoption by the ExCOP, but failed to pass it. The main areas of controversy were trade issues, treatment of commodities and domestic vs. international regulatory regimes. The continued debate on a protocol on biosafety will be transmitted to the resumed ExCOP session, no later than the fifth meeting of the Conference of the Parties.[7] Although the biosafety protocol has not yet been adopted, this attempt has catalyzed the attention of the biotechnology industry and of countries which have advanced biotechnology, in particular the U.S., because such a legally-binding treaty will greatly affect an individual nation's behavior and its domestic policies on biotechnology in the next century.

Issues of Intellectual Property Rights

The issue of intellectual property rights (IPRs) is a controversial subject in the context of the CBD, involving the developed nations (the North)—and generally those nations with advanced biotechnology— vis-à-vis the developing nations (the South)—generally nations endowed with rich genetic resources. The North wants stricter IPRs on new biotechnology discoveries, which may guarantee the biotech industry the recovery of their investments and costs, plus profits. In contrast, the South complains of inequitable sharing of benefits and lack of guarantees for compensation for the utilization of their genetic resources.[8]

The issue of the protection of IPRs on biotechnology is not an isolated phenomenon but is linked with issues of equitable benefit-sharing, compensation for traditional indigenous knowledge, community rights on the ownership of genetic resources, and transfer of technology. Therefore, the South adheres adamantly to the concept of a package deal, that IPRs must be dealt with as a cluster of all related issues, whereas the North, in particular U.S. and OECD member nations, argue that IPRs must be treated as a separate issue.

In the past, six major international agreements provided the policy framework for international patent law (from the Paris Convention in 1884, to the establishment of the World Intellectual Property Organization in 1970). More recently, adequate systems of intellectual property rights are being seen as an important component of free trade and, as such, are increasingly being dealt with in the World Trade Organization and GATT-related issues.

Traditionally, these intellectual property policies were generally thought to be relevant only to industrial application, and not to the store of valuable knowledge held by indigenous peoples around the world. Several of the international agreements and prescriptions emanating from the Earth Summit, especially the CBD and parts of Agenda 21, place strong emphasis on the protection of indigenous knowledge, on the awarding of benefits for the use of such knowledge, and on the transfer of technologies to the developing world, including those protected by patents and other intellectual property rights.

Novel forms of agreements are being negotiated, in different countries, among biotechnology companies, governments, NGOs, and the public, to govern bioprospecting, with the aim of achieving a proper balance between protection of biodiversity resources, protection of industry's interests, and protection of the public's rights to receive benefits from the exploitation of public marine resources / organisms. Evaluating the pros and cons of different types of agreements for bioprospecting and adapting appropriate forms to the special needs and requirements of the U.S. marine biotechnology industry in its operations in the U.S. and abroad is an important future challenge.

Work in progress

A detailed discussion of these issues may be found in *Policy Issues in the Development of Marine Biotechnology: Access, Biosafety, and Intellectual Property,* which is currently in preparation by the authors. The book, based on work funded by the Sea Grant program, examines the relevant international and national policy frameworks, analyzes the perspectives of various parties involved in these policy debates, including scientists working in the field, representatives of marine biotechnology companies, national

governments, international organizations, and international NGOs, especially from the developing world. Topics covered include the development of marine biotechnology around the world; current status of the marine biotechnology field; and issues of access to marine organisms, biosafety, and intellectual property rights. A set of findings and recommendations to address policy issues in each of the areas noted above that attempt to balance the competing interests at stake are also presented.

Notes

1. FCCSET, (Federal Consulting Council for Science, Engineering, and Technology), Committee on Life Science and Health. *Biotechnology for the 21st Century: Realizing the Promise*. Washington, DC.: Government Printing Office, 1993; OTA (U.S. Congress Office of Technology Assessment). *New Developments in Biotechnology*. U.S. Government Printing Office, Washington, DC., 1988; Rudolph, F. B. and McIntire, L. V. (eds.). *Biotechnology: Science, Engineering, and Ethical Challenges for the 21st Century*. Joseph Henry Press: Washington DC., 1996.

2. Jeremy Rifkin. *The Biotech Century: Harnessing the Gene and Making the World*. New York: Tarcher / Putnam, Inc. 1998, p. xii.

3. D. H. Attaway and O. R. Zaborsky. (eds). *Marine Biotechnology: Volume I, Pharmaceuticals and Bioactive Natural Products*. New York: Plenum. 1993.

4. P. Weber. "Abandoned seas: Reversing the decline of the oceans." *World Watch*. Paper 116, November, 1993, p.5 and D. A. Powers "New frontiers in marine biotechnology: Opportunities for the 21st century." In: *Marine Biotechnology in the Asian Pacific Region* (eds). C. G. Lundin and R. A. Zilinskas. The World Bank and SIDA. Stockholm. 1995, p. 17.

5. NSTC (National Science and Technology Council). *Biotechnology for the 21st Century: New Horizons*. A Report from the Biotechnology Research Subcommittee under Committee on Fundamental Science, National Science and Technology Council, July, 1995, p. 49.

6. The Convention on Biological Diversity was opened for signature at the Earth Summit in Rio de Janeiro, Brazil, on 5 June 1992 and entered into force on 29 December 1993.

7. hangbo Bai, Stas Burgiel, Chad Carpenter, Joanna Depledge, Leila Mead, and Lavanya Rajamani. "Report of the BSWG-6 and ExCOP Session to CBD," *Earth Negotiations Bulletin*, Vol. 09, No. 117.

8. Raustiala, K. and Victor, D.G. "Biodiversity since Rio: The future of the Convention on Biological Diversity." *Environment*, vol. 38, no. 4:17-45 (1996).